MEMORANDUM RECOMMENDING APPROVAL (MRA) FOR ORIGINAL AND SUPPLEMENTAL NEW ANIMAL DRUG APPLICATIONS (NADA)

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I. PURPOSE

This document provides instructions on how to use the office template to format and prepare a Memorandum Recommending Approval (MRA) for a New Animal Drug Application (NADA). An MRA should always be part of the approval package for an NADA.[1,2]

II. SUMMARY OF PROCEDURE

A. An MRA briefs the individual signing the approval (i.e., the Center Director, Office Director, or Director of the Division of Manufacturing Technologies) on the basis for the recommendation.

B. The "preparer" for purposes of this document refers to a reviewer, consumer safety officer (CSO), or other individual designated by the division to prepare the approval package for an application.

C. The preparer should use the office template to create an NADA MRA. Instructions for using the template follow in Section V.

[1] See P&P 1243.3800.
[2] MRAs for labeling and regulatory supplements as defined in 514.8(c)(3)(i) and 514.8(c)(3(ii) are covered elsewhere. Do not use this P&P for labeling and regulatory supplements. Consult your team leader or division director and the P&P Manual for P&Ps on labeling and regulatory supplements.

D. Team Leaders and Division Directors are responsible for ensuring that the correct version of the office template was used to create the NADA MRA and confirming the accuracy of the dates and submission codes referenced in the MRA. The Quality Assurance Team is no longer responsible for confirming the accuracy of this information.

III. PURPOSE OF AN MRA

An MRA is always part of an approval package for an NADA and briefs the individual signing the approval (i.e., the Center Director, Office Director, or Director of the Division of Manufacturing Technologies) on the basis for our recommendation to approve an NADA. The MRA incorporates by reference the data, information, and reviews that support our recommendation.

IV. WHO IS RESPONSIBLE FOR CREATING THE MRA USING THE OFFICE TEMPLATE

The preparer of the MRA is the reviewer, consumer safety officer (CSO), or other individual designated by the division to prepare the approval package for an application.

You, throughout this document refers to the preparer of the approval package. When you are preparing the final approval package, you should refer to P&Ps 1243.3010 and 1243.3030.[3]

V. INSTRUCTIONS FOR USING THE OFFICE TEMPLATE TO CREATE THE MRA

Use the office template to create the NADA MRA. Instructions for finding and using templates are located on the ONADE Reviewer's Reference Page under Review Aids/Approved Products on the ONADE Templates page.

A. General instructions for using the MRA template

1. Words not in italics or brackets, (i.e., < >), in the MRA are boilerplate and should be included in your MRA verbatim.

[3] P&P 1243.3010 discusses the format and style conventions for all letters issued by the office and P&P 1243.3030 discusses how to final out a submission and explains that you print the first page of the final MRA on official blue letterhead paper and any subsequent pages on quality bond paper.

2. Words in bracketed italics may provide instruction, describe the information you should provide, or may give examples of the type of information that you should include in a particular portion of the MRA.

3. Where you see brackets, you will provide information relating to your specific application.

4. You should include all eighteen sections (#1-18) identified in the template in each MRA. For each section, include the boilerplate language or appropriate information described in the NADA MRA template.

5. The trademarked portion of the proprietary name(s) (the part preceding the trademark symbols (i.e., ® or TM)) should appear in ALL CAPITAL letters without the symbols. You should write the remaining part of the name in lower case letters with the first letter of each word capitalized. If there is no trademark symbol, then you should write the entire proprietary name in lower case letters with the first letter of each word capitalized.

6. Do not include copies of any referenced documents that were not created as part of the current NADA submission. For example, copies of technical section complete letters, reviews associated with previously completed technical sections, FOI Summaries or FEDERAL REGISTER notices for previous approvals.

B. The "To" line of the MRA

1. Original NADA approvals

   Address the MRA to the Center Director, through the Director, Office of New Animal Drug Evaluation (ONADE).

2. Supplemental NADA approvals

   You will address most MRAs for supplemental approvals to the Director, ONADE, from the appropriate Division Director, except for:

   a. Supplements that would approve a new claim, new species, or change in Rx/OTC status will be addressed to the Center Director, through the Director, ONADE; and

b. Manufacturing supplemental approvals will be addressed to the Director, Division of Manufacturing Technologies.

VI. DISTRIBUTION COPIES

We no longer distribute paper copies of the MRA. You will fill in the appropriate application number in the cc: block of the office template to ensure that the paper copy is filed to the appropriate administrative file.

VII. REFERENCES

CVM Program Policy and Procedures Manual

1240.2325, CVM Guidance on Media Inquiries

1243.3030, Completing Final Action Packages for STARS Submissions

1243.3800, Approval Process and Approval Package

1243.5761, Freedom of Information Summary for an NADA

1243.5780, Exclusivity Wording for Use in the Following Documents: Memorandum Recommending Approval and Letter to Applicant

VIII. VERSION HISTORY

November 16, 2001 - ONADE Reviewers Manual revised and incorporated into CVM's Program Policy and Procedures Manual; this is the original P&P version

September 7, 2006 - Revised to include changes agreed upon by ONADE Management and to include some instructions for the template. The P&P no longer includes the standardized language for the MRA because it is included in the office template.